



DEPARTMENT OF HEALTH & HUMAN SERVICES

P970034
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rick Aguilera
Executive Vice President/ COO
Ophthalmic Innovations International, Inc.
500 North Claremont Blvd.
Claremont, CA 91711

SEP 25 1998

Re: P970034
Ultraviolet-Absorbing Polymethylmethacrylate (PMMA) Posterior Chamber
Intraocular Lenses (IOLs), Models RS-50B, RS-55B, RS-60B, and RS-65
Filed: July 21, 1997
Amended: August 12 and 18, and November 10, 1997, and January 26, April 30, and
September 8, 1998

Dear Mr. Aguilera:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Ophthalmic Innovations International, Inc. ultraviolet-absorbing PMMA posterior chamber IOLs, Models RS-50B, RS-55B, RS-60B, and RS-65. These devices are indicated for the visual correction of aphakia in persons 60 years of age or older, who are undergoing extracapsular cataract extraction and primary lens implantation. The intraocular lens is intended to permanently replace the natural cataractous crystalline lens and to restore useful vision. It is intended for capsular bag placement only. The devices are available in a range of powers from 4 diopters (D) to 34 D in 0.5 D increments. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the devices upon receipt of this letter.

The sale, distribution, and use of these devices are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the devices, the devices are further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

1. Registration of all patients receiving the above-reference intraocular lens must be continued and the data base shall be maintained indefinitely, or until the

applicant is otherwise notified.

2. A way of facilitating adverse reaction reporting, such as an 800 telephone number, must be maintained.

Expiration dating for this device has been established and approved at five years.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

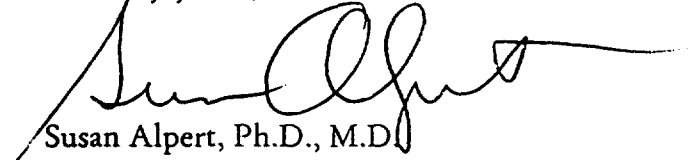
All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

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If you have any questions concerning this approval order, please contact Ms. Claudine Krawczyk at (301) 594-2053.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Susan Alpert', with a long horizontal flourish extending to the right.

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effectuated" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effectuated" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effectuated." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

- (1) May have caused or contributed to a death or serious injury; or
- (2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW

Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P970034
Date Filed: July 21, 1997
Date Approved: SEP 25 1998
- B. Device Generic Name: Ultraviolet-Absorbing Posterior Chamber Intraocular Lens (IOL)
- C. Device Trade Name: Models RS-50B, RS-55B, RS-60B, and RS-65 IOLs
- D. Applicant's Name and Address: Ophthalmic Innovations International (OII)
500 North Claremont Blvd.
Claremont, CA 91711
- E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection (Ophthalmic Innovations International): January 8, 1998
Date of Inspection (Griffith MicroScience, Inc.): May 1, 1998
Conclusion: Both manufacturing sites were found to be in compliance with device GMP requirements.
- F. Ophthalmic Devices Panel (Panel):
Date Reviewed: October 19, 1989 (P880082)
Recommendation: Approval

II. INDICATIONS

OII intraocular lenses are indicated for the visual correction of aphakia in persons 60 years of age or older, who are undergoing extracapsular cataract extraction and primary lens implantation. The intraocular lens is intended to permanently replace the natural cataractous crystalline lens and to restore useful vision. It is intended for capsular bag placement only.

III. SUMMARY OF CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH) DECISION

The application includes by reference the data in PMA P880082 and related supplements for the IOLs submitted by Eye Technology, Inc. and approved by FDA on June 13, 1990. Eye Technology, Inc. has authorized Ophthalmic Innovations International to incorporate by reference the information contained in its approved PMA and related supplements to manufacture the device.

CDRH approval of the Ophthalmic Innovations International PMA is based on (1) the safety and effectiveness data contained in PMA P880082 and related supplements, (2) the additional test data contained in the OII PMA P970034 to demonstrate equivalence of manufacturing methods and IOL design, and (3) the results of the FDA inspection of the manufacturing facilities. A summary of safety and effectiveness data and the final labeling for the Eye Technology, Inc. IOLs are attached.

On October 19, 1989, the Panel reviewed the PMA for the Eye Technology, Inc. IOLs and concluded that the PMA contained valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the devices under the prescribed indications for use. CDRH approved this PMA (P880082) in a letter to the PMA applicant dated June 13, 1990 and signed by the Director, Office of Device Evaluation. In accordance with CDRH's announced policy (4/18/86 PMA Guidance Memorandum #86-4), this licensing PMA was not taken to the Panel. CDRH approved this PMA (P970034) is a letter to the PMA applicant dated SEP 25 1998 and signed by the Director, Office of Device Evaluation.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P880082
Date Filed: December 27, 1988
Date Approved: JUN 13 1990
- B. Generic Name of Device: Ultraviolet-Absorbing Posterior Chamber
Intraocular Lenses
- C. Trade Name of Device: Models 14760-5 and 14760-6
- D. Applicants Name and Address: Eye Technology, Inc.
1983 Sloan Place
Saint Paul, Minnesota 55117
- E. Good Manufacturing Practice (GMP) Inspections:
March 4 and 5, 1990
- Conclusion: The manufacturing sites were found to be in
compliance with device GMP requirements.
- F. Ophthalmic Devices Panel (Panel)
Dates Reviewed: October 19, 1989
Recommendation: Approval

II. INDICATIONS

These devices are intended to be used for primary implantation for the visual correction of aphakia in patients 60 years of age or older where a cataractous lens has been removed by extracapsular extraction methods. These lenses are intended to be placed in the capsular bag.

III. SUMMARY

The applicant has performed non-clinical and clinical testing on these devices in accordance with the FDA guidance document for testing intraocular lenses dated June 9, 1980. Non-clinical testing demonstrates the safety and effectiveness of these devices from microbiology, toxicology, chemistry, engineering, and manufacturing perspectives. Data on 504 patients followed postoperatively for 12-14 months were clinically and statistically evaluated. Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of these devices, i.e., complications and adverse reactions and visual acuity results, compare favorably with FDA's 1983 IOL "grid" of historical data.

IV. SAFETY AND EFFECTIVENESS DATA

A. Non-Clinical Studies

The applicant conducted a battery of in-vivo and in-vitro acute and chronic toxicity tests that establishes the biocompatibility of the lens materials. Additionally, data from chemistry and engineering analyses further demonstrate the suitability of the materials and overall device design for use in an intraocular lens. The adequacy of the manufacturing process, including sterilization, was established through review of manufacturing information in the PMA as well as through an on-site inspection.

B. Clinical Studies

	P880082 (n=504)	Grid
Visual Acuity		
20/40 or better		
Overall	92.1% (464/504)	88.0%
Best-Case	98.2% (333/339)	94.0%
Adverse Reactions		
Acute Corneal Decompensation	0.0%	0.2%
Hypopyon	0.0%	0.4%
Intraocular Infection	0.0%	0.1%
Surgical Reintervention	1.0%	2.0%
Postoperative Complications		
Persistent Corneal Edema	0.0% (0)	0.6%
Persistent Iritis	1.0% (5)	1.0%
Cumulative Lens Dislocation	0.2% (1)	0.4%
Cumulative Hyphema	1.6% (8)	1.0%
Persistent Secondary Glaucoma	0.6% (3)	0.5%
Cumulative Macular Edema	6.5% (33)	3.5%
Persistent Macular Edema	0.8% (4)	0.8%
Cumulative Pupillary Block	0.2% (1)	0.3%
Persistent Cyclitic Membrane	0.0% (0)	<0.1%
Persistent Vitritis	0.0% (0)	0.1%
Cumulative Endophthalmitis	0.0% (0)	0.1%
Cumulative Retinal Detachment	0.2% (1)	0.5%

*Best Case: Excludes patients with preoperative ocular pathology or macular degeneration at any time.

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V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel reviewed the PMA and concluded that the PMA contained valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the devices under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated JUN 13 1990 and signed by the Director, Office of Device Evaluation.

EYE TECHNOLOGY, INC.

Description:

The Eye Technology, Inc. Posterior Chamber Intraocular Lenses are designed for the correction of aphakia with an optical device implanted entirely within the posterior chamber of the human eye. The posterior chamber lenses have an optical portion consisting of UV-absorbing polymethylmethacrylate. Clinical quality polymethylmethacrylate is a material that has been used in intraocular prosthetic devices for more than 30 years.

POSTERIOR CHAMBER LENSES

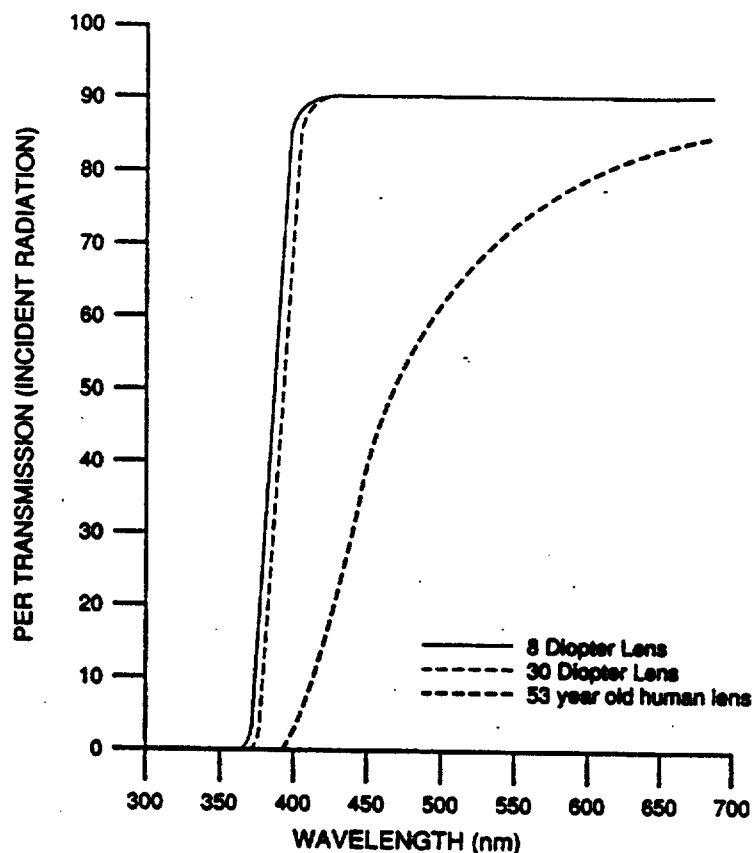
LENS OPTIC:

Material	- Rohm & Haas, UF-3, Ultraviolet absorbing, Polymethylmethacrylate (PMMA)
Specific Gravity	- 1.19
Index of Refraction	- 1.49
Configuration	- Plano-Convex, 6.0mm, 6.5mm, and 7.0mm in diameter
Dioptric Power	- +8.0 to +30.0 diopters in 0.5 increments
Positioning Holes	- 0 - 4 dependent upon Model
Haptic Angulation	- 0 degree to 10 degree dependent upon Lens Model
Overall Diametric Length	- 13.5 mm to 14.0 mm dependent upon Lens Model

HAPTICS:

Material	- Polymethylmethacrylate
Color	- Blue or Clear PMMA

EYE TECHNOLOGY INC. U.V. TRANSMITTANCE



378 nm—ten percent (10%) transmittance cut-off

(THINNEST 8.0 DIOPTER)

388 nm—ten percent (10%) transmittance cut-off

(THICKEST 30.0 DIOPTER)

415 nm—ten percent (10%) transmittance cut-off

Boettner, E.A. and Wolter, J.R.,
Transmission of the Ocular Media,
Invest. Ophthalmol. 1:776-783, 1962

ACTION

The lens is positioned posterior to the iris. This position allows the optical magnification of the intraocular lens to replace the function of the natural crystalline lens.

The desired postoperative visual results can be achieved most satisfactorily only when optimum lens power is calculated preoperatively, the visual goals are clearly understood, pre-existing astigmatism is neutralized by attention to corneal closure, and surgically induced astigmatism is minimized by careful surgical techniques and postoperative monitoring.

Lens power calculation methods are described in the following references:

1. Binkhorst, R.D.: Intraocular Lens Power Calculation Manual, New York, Richard D. Binkhorst, 1978.
2. Retzlaff, J., Sanders, D., and Kraff, M.: A Manual of Implant Power Calculation.

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INDICATIONS: These posterior chamber lens models are intended to be used in primary implantation for visual correction of aphakia in patients 60 years of age or older when cataractous lens has been removed by extra capsular cataract extraction method. The lens is intended to be placed in the capsular bag.

CAUTION: Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight: .

1. Congenital bilateral cataracts.
2. Recurrent anterior or posterior segment inflammation of unknown etiology.
3. Where the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
4. Surgical difficulties at the time of cataract extraction which might increase the potential for complications, e.g., persistent bleeding, significant iris damage, uncontrollable positive pressure or significant vitreous prolapse or loss.
5. Patients with only one eye with potentially good vision.
6. Medically uncontrollable glaucoma.
7. Corneal endothelial dystrophy.
8. Proliferative diabetic retinopathy.
9. Implantation of intraocular lenses should not be performed in patients under 18 years of age.
10. The effectiveness of this lens in reducing the incidence of retinal disorders has not been established.

WARNINGS:

1. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to, the following: lens dislocation, manifestations of inflammation, corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary or cyclitic membrane, iris prolapse, hypopyon and transient or persistent glaucoma.
2. The safety and efficacy of these posterior chamber lenses have not been established if placed in the anterior chamber. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe. Such implantation should take place under investigational protocol approved by FDA.
3. The safety of intraocular lens implants has not been substantiated in patients with pre-existing ocular conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, previous retinal detachment, or iritis, etc.). Physicians considering lens implants in such patients should explore the use of

alternative methods of aphakic correction and consider lens implants only if alternatives are deemed unsatisfactory to meet the needs of the patient. 4. The long-term effect of intraocular lens implants has not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis. 5. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, glaucoma and chronic drug miosis, may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.

6. Patients who experience surgical complications associated with the cataract extraction procedure (posterior capsule rupture, detached Descemet's membrane, anterior chamber bleeding, and vitreous bulge or loss), may experience a higher incidence of inflammatory responses which generally are transient in nature.

7. Patients who experience postoperative complications such as macular edema, iritis, corneal edema, vitritis, retinal detachment and lens dislocation may experience poorer visual outcome.

8. A need for secondary iridectomy for pupillary block may be prevented by one or more iridectomies at time of implantation.

PRECAUTIONS:

1. Do not resterilize these intraocular lenses by any method (See RETURN LENS POLICY).
2. Do not store lenses at temperatures over 110 degrees Fahrenheit.
3. Use only sterile intraocular irrigating solutions, e.g., balanced salt or normal saline solution, to rinse and/or soak lenses.
4. A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted on numerous surgical implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

DIRECTIONS FOR USE:

1. Check the label on the lens package for proper lens model, diopter power and expiration date.
2. Open the package using a sterile technique, and without touching the optic portion of the lens, transfer the lens into a container of sterile intraocular irrigating solution.
3. There are several various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.

NOTE: Because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING

Registration: Each patient who receives an Eye Technology, Inc. Posterior Chamber lens must be registered with Eye Technology, Inc. at the time of lens implantation.

Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens box and mailing it to Eye Technology, Inc.

Patient registration is essential for Eye Technology, Inc.'s long-term patient follow-up program and will assist Eye Technology, Inc. in responding to Adverse Reaction Reports and/or potentially sight-threatening complications.

An Implant Identification Card is supplied in the lens package. This card should be given to the patient with instructions to keep it as a permanent record of the implant, and to show the card to any eye care practitioner seen in the future.

Reporting: Adverse reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported to Eye Technology, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation.

Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with all styles of posterior chamber lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

Physicians should use the following toll-free numbers when reporting Adverse Reactions or potentially sight-threatening complications involving Eye Technology, Inc. intraocular lenses:

National: (800)328-9060
In Minnesota: (612)774-9060

CLINICAL EXPERIENCE: The clinical studies on the lenses were conducted at various times beginning in January 1987 and extending through September 1988. The results achieved by the patients, in their respective cohorts (Table 1), who were followed for one year, provide the basis for the data which were used to determine that these lens styles were safe and effective devices for the visual correction of aphakia in patients 60 years of age or older. The data for all styles of Eye Technology, Inc. Posterior Chamber lenses is comparable. Table 1 provides information relative to the Core Cohort study populations.

TABLE 1
Patient Demographics Model 14760

PATIENT POPULATION		504 LENSES
Patients with Pre-existing Macular Degeneration (%)		7.7%
Additional Patients with Other Pre-existing Conditions* (%)		19.7%
Gender:	Males (%)	34%
	Females (%)	66%
Race:	Caucasian (%)	91.7%
	Black (%)	6.2%
	Other (%)	2.2%

VISUAL ACUITY: Postoperative visual acuity (12 months or longer following lens implantation) is presented in Table 2. Younger patients have achieved better postoperative results; this is usually associated with degenerative factors normal in older patients.

Preoperative ocular pathology can diminish expected visual outcome. This factor should be considered carefully prior to making the decision to implant the lens.

The overall incidence of surgical problems was low. It is generally accepted, however, that certain surgical problems may lead to poorer visual acuity. Medical judgment must be exercised to determine if a lens should be implanted when surgical problems occur.

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Patients who experience sight-threatening complications may have a higher risk of experiencing poorer visual outcome than patients without sight-threatening complications.

TABLE 2
Best Visual Acuity* of Patients in Core Cohort
Model 14760

Age	20/40 or Better		20/41-20/80		20/81-20/100		20/101-20/200		Worse Than 20/200	
	#	%	#	%	#	%	#	%	#	%
< 60	22	100.00	0	0.00	0	0	0	0	0	0.00
60-69	83	98.81	1	1.19	0	0	0	0	0	0.00
70-79	144	98.63	1	0.68	0	0	0	0	1	0.68
80 +	84	96.55	3	3.45	0	0	0	0	0	0.00
Total	333	98.23	5	1.47	0	0	0	0	1	0.29

*Patients with macular degeneration or pre-existing ocular pathology such as glaucoma, previous glaucoma filtering surgery, chronic drug miosis, amblyopia, diabetic retinopathy and previous retinal detachment have been excluded.

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COMPLICATIONS: Eleven (11) complications following cataract extraction and/or intraocular lens implantation have been identified by the Food and Drug Administration as potentially sight-threatening. The rate of these complications one year postoperatively is shown below in Table 3.

TABLE 3
Cumulative and Persistent Potentially Sight-
Threatening Complications
Model 14760

Complication	Cumulative Incidence		Incidence at Months 12-14	
	#	%	#	%
Hyphema	8	1.6	0	0.0
Macular Edema	33	6.5	4	0.8
Pupillary Block	1	0.2	1	0.2
Secondary Glaucoma	11	2.2	3	0.6
Cyclitic Membrane	1	0.2	0	0.0
Vitritis	1	0.2	0	0.0
Endophthalmitis	0	0.0	0	0.0
Retinal Detachment	1	0.2	0	0.0
Persistent Corneal Endema	N/A	N/A	0	0.0
Persistent Iritis	N/A	N/A	5	1.0
Malpositioned Lens	1	0.2	0	0.0
Lens Dislocation	1	0.2	0	0.0

A total of 55 Cohort patients experienced one or more sight-threatening complications; however, these complications occurred early in the postoperative time frame. Only 13 Cohort patients (2.5%) were reported to have these complications 12-14 months after surgery.

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ADVERSE REACTIONS: Adverse Reactions were reported at the following rates for the Style 14760 Posterior Chamber lenses.

ADVERSE REACTIONS	NUMBER OF OCCURRENCES
Study <u>Model 14760</u>	
Hypopyon	0
Intraocular Infection	0
Acute Corneal Decompensation	0
Secondary Surgical Intervention	5
Other Adverse Reactions	0
Reasons for Surgical Intervention:	
a) Decentered	3
b) Wound Leak	1
c) Anterior Capsular Tag to Corneal Wound	1

As of November 6, 1988, 5,094 Model 14760 lenses have been implanted including core and adjunct patients. The overall incidence of adverse reactions is .12%.

HOW DEVICE SUPPLIED: The intraocular lenses are supplied sterile, in dry form, in individually wrapped packages. The lens container is sealed within a sterile pouch and placed in a protective box together with labels and product information.

Open the pouch over a sterile field and remove the lens case. While holding the lens case, correct side up, over the sterile field, open the case and gently free the Eye Technology, Inc. intraocular lens from the case, being certain not to damage either the supporting loops of the lens or its highly polished optical surface.

EXPIRATION DATE: The inner package has been sterilized in ethylene oxide under special temperature conditions, assuring sterility if seal is intact and pouch is not punctured, until the expiration date marked on the package label. The lens should not be used after indicated date.

RETURN LENS POLICY: Lenses returned for any reason must be accompanied by an authorization number obtained by calling our Customer Service Department. Please print the authorization number on the outside of the shipping box. Returned lenses should be shipped by an insured, traceable method. No credit can be given for returned lenses lost or damaged in shipment.

CAUTION: United States law restricts this device to sale by or on the order of a physician.

REFERENCES:

- Jaffe, N.S. Suggested guidelines for intraocular lens implant surgery. Archives of Ophthalmology, 1976, 94, 214-216.
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- Shepherd, D.D. The intraocular lens manual. (4th ed.) Santa Maria, CA: Astro Printers, 1982.
- Girard et al, Ophthalmic Surgery, Vol. 14, No. 4, Apr. 1983.
- Willis et al, Ophthalmic Surgery, Vol. 16, No. 2, Feb. 1985.
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- Jaffe, N.S. et al: Pseudophakos. The C.V. Mosby Company, St. Louis, 1978, p. 4, 12.

PACKAGE INSERT

Prescription Device

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description

This OII posterior chamber intraocular lens is an optical lens manufactured from ultraviolet-light absorbing polymethylmethacrylate and is designed to be positioned posterior to the iris in the capsular bag.

Indications

This OII intraocular lens is indicated for the visual correction of aphakia in persons 60 years of age or older, who are undergoing extracapsular cataract extraction and primary lens implantation. The intraocular lens is intended to permanently replace the natural cataractous crystalline lens and to restore useful vision. It is intended for capsular bag placement only.

Warnings

1. Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
 - a. Recurrent severe anterior or posterior segment inflammation or uveitis.
 - b. Pre-existing ocular diseases (endothelial corneal dystrophy, recurrent inflammation or uveitis, chronic drug miosis, proliferative diabetic retinopathy, previous retinal detachment, suspected microbial infection).
 - c. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
 - d. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, non-intact posterior capsule or zonules, significant vitreous prolapse or loss).
 - e. Circumstances that would result in damage to the endothelium during implantation.
 - f. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
 - g. Small-optic IOLs (<5.5mm diameter), which may, if slightly decentered, result in glare or other visual disturbances under certain lighting conditions.
 - h. The lens is not indicated for children under the age of 2 years.
2. Long-term effects of intraocular lens implantation were not studied in the clinical investigation.
3. During the clinical investigation, insufficient clinical data on ciliary sulcus placement were collected to demonstrate safety and efficacy. The lens is intended for capsular bag placement only.

4. Implantation of posterior chamber lenses into the anterior chamber has been shown to be unsafe and should not be performed.
5. The effectiveness of UV-absorbing lenses in reducing the incidence of retinal disorders has not been established.

Precautions

1. Do not resterilize the lens; institutional sterilizers may produce undesirable side effects in the IOL. See *Returned Lens Policy*. ②
2. Use only sterile irrigating solutions, i.e. normal saline or balanced salt solution, for rinsing or soaking of lens.
3. Do not store lens at temperatures exceeding 110°F.

Adverse Events (Complications and Adverse Reactions)

Eleven complications and four adverse reactions following cataract extraction/IOL implantation surgery have been identified by the Food and Drug Administration as potentially sight threatening. The complications and adverse reactions experienced during the clinical trial of Model 14760 are presented in Tables 1 and 2.

TABLE 1: POTENTIALLY SIGHT-THREATENING COMPLICATIONS
(CORE COHORT: N=504)

COMPLICATION	CUMULATIVE INCIDENCE		PERSISTENT INCIDENCE		FDA GRID INCIDENCE	
	#	%	#	%	CUMULATIVE	PERSISTENT
HYPEREMA	8	1.6	0	0.0	1%	N/A
CYSTOID MACULAR EDEMA	33	6.5	4	0.8	3.5%	0.8%
PUPILLARY BLOCK	1	0.2	1	0.2	0.3%	N/A
SECONDARY GLAUCOMA	11	2.2	3	0.6	N/A	0.5%
CYCLITIC MEMBRANE	1	0.2	0	0.0	N/A	<0.1%
VITRITIS	1	0.2	0	0.0	N/A	0.1%
ENDOPHTHALMITIS	0	0.0	0	0.0	<0.1%	N/A
RETINAL DETACHMENT	1	0.2	0	0.0	0.5%	N/A
CORNEAL EDEMA	N/A	N/A	0	0.0	N/A	0.6%
IRITIS	N/A	N/A	5	1.0	N/A	1.0%
LENS DISLOCATION	1	0.2%	N/A	N/A	0.4%	N/A
MALPOSITIONED LENS	1	0.2%	0	0.0	N/A	N/A

A total of 55 cohort patients experienced one or more sight-threatening complications, most of which occurred in the early postoperative period. Only 13 cohort patients (2.5%) were reported to have these complications 12-14 months after surgery.

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**TABLE 2: ADVERSE REACTIONS
(ALL CORE PATIENTS N=642)**

ADVERSE REACTION	OCCURRENCE		FDA GRID
	#	%	%
HYPOPYON	0	0.0	0.4%
INTRAOCULAR INFECTION	0	0.0	0.1%
ACUTE CORNEAL DECOMPENSATION	0	0.0	0.2%
SECONDARY SURGICAL INTERVENTION	6	0.9%	2%
REPAIR LENS DECENTRATION	3		
REPAIR WOUND LEAK	1		
REPAIR ANTERIOR CAPSULE TAG TO CORNEAL WOUND	1		
LENS DISLOCATION & EXCHANGE TO ACL	1		

As of November 6, 1988, 5094 investigational lenses were implanted in the core and adjunct studies. The overall incidence of adverse reactions is 0.16%

Clinical Trial

A clinical investigation of intraocular lens Model 14760 serves as the basis for concluding that the design of this OII lens model is safe and effective for the visual correction of aphakia. That clinical trial was initiated in January 1987 and patients were accrued through September 1988.

**TABLE 3: PATIENT DEMOGRAPHICS
(CORE COHORT N=504)**

PATIENT POPULATION		PERCENT (%) OF IMPLANTED EYES
GENDER	Male	34.0%
	Female	66.0%
RACE	Caucasian	91.7%
	Black	6.2%
	Other	2.2%
PREOPERATIVE PATHOLOGIES		
Macular degeneration ¹		7.7%
Other ocular conditions		19.7%

¹ Macular degeneration at any time (pre- or post-operatively)

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The results achieved by 504 patients implanted with lens Model 14760 followed for one year serve as the basis for concluding that the design of this OII lens model is safe and effective for the visual correction of aphakia.

**TABLE 4: BEST CASE VISUAL ACUITY
at 12-14 months postoperatively
(Best case* core cohort N=339)**

AGE	20/40 or better		20/41 - 20/80		20/81 - 20/100		20/101 - 20/200		Worse than 20/200		FDA Grid 20/40 or better
	#	%	#	%	#	%	#	%	#	%	%
<60 years	22	100.0	0	0	0	0	0	0	0	0	96.9
60 - 69 years	83	98.8	1	1.2	0	0	0	0	0	0	93.8
70 - 79 years	144	98.6	1	0.7	0	0	0	0	1	0.7	94.9
80+ years	84	96.6	3	3.5	0	0	0	0	0	0	87.9
Total	333	98.2	5	1.5	0	0	0	0	1	0.3	94.0

* Patients with macular degeneration or pre-existing ocular pathology such as glaucoma, previous glaucoma filtering surgery, chronic drug miotic, amblyopia, diabetic retinopathy, and previous retinal detachment have been excluded.

Younger patients achieved better post-operative outcomes, generally due to the absence of degenerative factors commonly associated with older patients. Preoperative ocular pathology can diminish expected visual outcome. The overall incidence of surgical problems was low. It is generally accepted that certain surgical problems may lead to poorer visual acuity. Medical judgement must be exercised to determine if a lens should be implanted in patients either with preoperative pathologies or with surgical problems. Patients who experience sight-threatening complications may have a higher risk of experiencing poorer visual outcome than patients without such complications.

Detailed Device Description

The posterior chamber IOL is manufactured from a single piece of UV-PMMA with a biconvex optic and haptics in one of several modified-C configurations. Depending upon model, optic diameter ranges from 5.0 to 6.5 mm, overall diameter ranges from 12.5 to 13.5 mm, and haptic angulation ranges from 0° to 10°. None of the models has positioning holes. Each model is available in dioptric powers of 4D through 34D in 0.5 diopter increments.

The UV-PMMA material has a specific gravity of 1.19, a refractive index of 1.492, and light transmittance of 10% at 388 nm.

Insert graph
(light transmittance vs wavelength)

(include wording to side of graph
too.)

Directions for Use

1. A high level of surgical skill and experience is required for intraocular lens implantation.
2. Confirm the lens type, dioptric power, haptic configuration, and expiration date on the lens box.
3. Open the lens pouch in a sterile environment using sterile technique.
Caution: Do not use lens if the pouch or case has been damaged, as its sterility may be compromised.
4. The lens may be soaked or rinsed with a sterile irrigating solution.
5. The lens may have an electrostatic charge, causing particles to adhere to its surface; rinsing with sterile irrigating solution should remove such particles from the lens.

Lens Power Calculations

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

1. Hoffer KJ, *The Hoffer Q Formula: a comparison of theoretic and regression formulas*, Journal of Cataract and Refractive Surgery, Vol. 19, pp. 700-712, 1993; ERRATA, Vol.20, pp 667, 1994.
2. Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, and Ruiz RS, *A three-part system for refining intraocular lens power calculations*, Journal of Cataract and Refractive Surgery, Vol.14, pp 17-24, 1988.
3. Holladay JT, *Standardizing Constants for Ultrasonic Biometry, Keratometry and Intraocular Lens Power Calculations*, accepted for publication Journal of Cataract and Refractive Surgery, November 1997.

4. Olsen T, Olesen H, Thim K, and Cordon L, *Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas*. Journal of Cataract and Refractive Surgery, Vol. 18, pp 280-285, 1992.
5. Retzlaff JA, Sanders DR, and Kraff MC, *Development of the SRK/T intraocular lens implant power calculation formula*, Journal of Cataract and Refractive Surgery, Vol. 16, pp 333-340, 1990, ERRATA. Vol. 16, pp528, 1990.

Patient Registration Instructions

Registration Each patient who receives an Ophthalmic Innovations International (OII) posterior chamber lens must be registered with OII at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens box and mailing it to OII. Implant registration is an FDA requirement.

Implant identification An Implant Identification Card is supplied in the lens package. This card should be given to the patient with instructions to keep it as a permanent record of the implant and, in the future, to show the card to eye care practitioners.

Adverse Event Reporting

Adverse reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity, or degree of incidence should be reported to OII Quality department at 1-800-291-0158. This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

How Supplied

OII intraocular lenses are supplied sterile and non-pyrogenic. Each unit is enclosed within its own lens case and sterilization pouch. Sterility is assured provided that the pouch seal has not been compromised and the pouch has not been punctured.

Expiration Date

The expiration date is clearly indicated on the outside of the box.

Returned Lens Policy

Lenses will be accepted at no charge for either replacement (at any time) or for exchange (within 90 days). Returned lenses should be packaged in their original case and must be accompanied by a *Returned Lens Authorization Number*, obtained from the OII Customer Service Department.

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2. Technical Service Note PX127, Third Edition, Imperial Chemical Industries PLC, 1961.
3. Clayman HM, *Ultraviolet-absorbing Intraocular Lenses*, Am Intraocular Soc. J. v10, 1984.
4. Peyman GA, Zak R, and Sloan H. *Ultraviolet-absorbing pseudophakos: An efficacy study*, Am Intraocular Implant Soc J. 9: 167-170, 1983.
5. Zigman S. *Photohazards of intraocular lens implants in aphakia*, Letter to the Editor, Am J. Ophthalmol 90(1): 114-115, 1980.
6. Mainster MA. *Spectral transmittance of intraocular lenses and retinal damage from intense light sources*, Am J. Ophthalmol 85: 167-170, 1978.
7. Peyman GA, Sloan HD, and Lim J. *Ultraviolet Light-Absorbing pseudophakos*, Am Intraocular Implant Society J 8: 357-360, 1982.
8. Boettner EA. *Spectral Transmission of the Eye, Final Report*, USAF Contract AF41 (609)-2966, USAF Aerospace Medical Division, Brooks Air Force Base, Texas, July 1967.

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